

Appl. Serial No. 10/603,254
Response dated August 22, 2005
Response to Office Action dated May 20, 2005

II. Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claims 1-75. (cancelled)

Claim 76. (currently amended) A controlled release oral solid dosage form comprising a therapeutically effective amount of lovastatin and a controlled release carrier, said dosage form increasing the bioavailability of lovastatin and not increasing the bioavailability of ~~lovastatin~~ lovastatin acid, as compared to the same amount of lovastatin administered in an immediate release dosage form, the dosage form providing a time to maximum plasma concentration (Tmax) at from about 10 to about 32 hours and a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 77. (previously presented) A controlled release oral solid dosage form of claim 76, wherein the bioavailability of lovastatin and its latent and active metabolites at steady state conditions is about 1.4 to about 2 fold the bioavailability attained by the same amount of lovastatin administered once daily in an immediate release dosage form, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 78. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form providing an AUC0-24h of lovastatin of greater than 100% of the AUC0-24h provided by the same amount of lovastatin administered in an immediate release dosage form, and said dosage form providing an AUC0-24h of lovastatin acid of less than 100% provided by the same amount of lovastatin administered in an immediate release dosage form, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 79. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after administration of a single dose providing a ratio of AUC_{0-24h} of lovastatin to AUC_{0-24h} of lovastatin acid of from about 1:1 to about 3.6:1, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 80. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after once daily administration for 28 days providing a ratio of AUC_{0-24h} of lovastatin to AUC_{0-24h} of lovastatin acid of from about 0.74:1 to about 2:1, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 81. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after administration of a single dose providing a ratio of C_{max} of lovastatin to C_{max} of lovastatin acid of from about 1.1:1 to about 5:1.

Claim 82. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after once daily administration for 28 days providing a ratio of C_{max} of lovastatin to C_{max} of lovastatin acid of from about 0.75:1 to about 3:1, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 83. (previously presented) The controlled release oral solid dosage form of claim 79, wherein the ratio is about 1.3:1.

Claim 84. (previously presented) The controlled release oral solid dosage form of claim 80, wherein the ratio is about 0.87:1.

Claims 85-87. (cancelled)

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Claim 88. (new) The controlled release oral solid dosage form of claim 76, wherein said controlled release carrier is incorporated into a matrix along with the lovastatin.

Claim 89. (new) The controlled release oral solid dosage form of claim 76, wherein said controlled release carrier is applied as a controlled release coating to the lovastatin.